Memorandum

Subject: Summary of Comments on April 10, 1995 Federal Register Notice of Proposed Rulemaking for the Hazardous Organic NESHAP: AD-FRL-5182-6

From: Jan Meyer
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To: Docket A-90-20

Ten letters were received on the proposed changes to the rule, which were published on pp. 18071 through 18078 of the April 10, 1995 Federal Register . Of these letters, only nine contained comments on the proposed amendments to the HON. Attachment A presents a list of the commenters on this Federal Register notice. In general, the comments were supportive of the proposed changes although a few of the letters contained suggestions for further improvements. The comment summaries are organized in the same order as the proposed amendments to the final rule.

1. Proposed removal of three polyether polyols from Table 1 of subpart F.

Comment : Two commenters (A-90-20: VI-D-14, VI-D-15) agreed that it was more appropriate for process units producing these products to be regulated with other polyether polyols processes under the source category "Polyether Polyols Production."

Response : The three chemical production processes (glycerol tri(polyoxypropylene)ether, polyethylene glycol, and polypropylene glycol) will be removed from the list of chemical production processes regulated by the HON. The rationale for this change is the same as discussed in the proposal to revise Table 1 of subpart F.

2. Proposal to Allow Consolidation of Equipment Leak Programs.

Comment: Several commenters (A-90-20: VI-D-14; VI-D-15; and VI-D-17) supported the proposed provision to allow consolidation of equipment leak programs under subpart H in lieu of complying with 40 CFR Part 60 subparts VV, GGG, or KKK or with 40 CFR Part 61 subparts F or J. One commenter (A-90-20: VI-D-14) also requested that the EPA clarify that such equipment would only be subject to subpart H and not subpart G. Another commenter (A-90-20: VI-D-17) remarked that having to comply with numerous equipment leak programs, all slightly different, was frustrating, confusing, and creates an unnecessary burden. For this reason, this commenter (A-90-20: VI-D-17) requested that the EPA expand the proposed list of programs to allow consolidation of programs required by 40 CFR Part 264 subparts AA, BB, and CC and 40 CFR Part 265 subparts AA, BB, and CC with 40 CFR Part 63 subpart H. The commenter argued that consolidating these programs would further reduce regulatory burden without diminishing protection of the environment.

Response: The EPA thinks that the proposed §63.160 (c) clearly stated that the owner or operator would be electing to comply with subpart H only, and not subpart G, for equipment already subject to an equipment leak program. Furthermore, the EPA does not expect there will be any confusion regarding the applicability of subpart G since that subpart is not cross referenced in §63.160 (c).

In response to the request that the EPA allow consolidation of the RCRA equipment leak programs, the EPA has also revised the proposed language in §63.160 (c) to include reference to 40 CFR Part 264 subpart BB or 40 CFR Part 265 subpart BB. This revision is appropriate because those subparts were modeled on the equipment leak provisions of Parts 60 and 61. Allowing compliance with subpart H only will simplify compliance at no environmental cost. The option to comply with subpart H has not extended 40 CFR Part 264 subpart AA and subpart CC because these rules apply to entirely different types of equipment than the provisions in 40 CFR Part 63 subpart H. The EPA does not believe that it would be useful to include these rules in this provision.

3. Proposed Clarification of the Term "Flow Indicator."

Comment: Two commenters (A-90-20: VI-D-14 and VI-D-15)

agreed that the proposed revision to the definition is necessary for the provisions to operate as the EPA originally intended. These commenters noted that the revisions will eliminate confusion and allow for more cost-effective compliance.

Response: None required.

4. Proposed Revisions to §63.166 Sampling Connection Systems.

Comment: Two commenters (A-90-20: VI-D-14; and VI-D-15) agreed with the proposed definition for sampling connection system. These commenters thought that the definition would clarify the requirements for this section and reduce burden. One commenter (A-90-20: VI-D-12) supported the effort to clarify

this term and also recommended that the EPA amend 40 CFR Part 60, subpart VV to include this definition.

Response: None required.

Comment: Three commenters (A-90-20: VI-D-14; VI-D-15; and VI-D-17) supported the proposal to identify additional facilities to which purged material may be sent for treatment or disposal. One of these commenters (A-90-20: VI-D-17) also requested that the EPA clarify that collected purge material may be transported to containers in "satellite accumulation areas" and "less than 90 day storage areas." This commenter (A-90-20: VI-D-17) was concerned that the proposed language in §63.166 (b)(4)(ii) could be misconstrued to require transfer of the purged material directly to a permitted TSDF rather than allowing transfer to a "satellite accumulation area" or "less than 90 day storage area" then to a permitted TSDF. This commenter (A-90-20: VI-D-17) noted that once material is placed in such a container or facility its proper handling and management is assured. The commenter (A-90-20: VI-D-17) requested that the EPA clarify this point in the final rule or in the preamble to the final rule.

A fourth commenter (A-90-20: VI-D-13) noted that the proposal to allow additional facilities to receive purged materials did not go far enough. The commenter (A-90-20: VI-D-13) argued that the proposal seems to be inconsistent in that purges of certain materials, if evaluated as process wastewater, would not be subject to control yet the proposed

revisions to §63.166 (b)(4)(i) would require such purges to be managed in controlled units. The commenter (A-90-20: VI-D-13) requested that sample purges of materials that are not listed in Table 9 of subpart G not be required to be managed in controlled waste management units since these materials have low emission potential when mixed with water.

Response: The EPA agrees with the commenter (A-90-20: VI-D-17) that transfer to a "satellite accumulation area" or to a "less than-90-day storage area" should be allowed. The language in §§63.160 (b)(4) and 63.166(b)(4)(ii) has been revised to clarify that it is permissible to store the collected purge material prior to transferring it to a permitted TSDF. There was never any intention that the material had to be transmitted directly to the TSDF.

The EPA also agrees with the suggestion that when certain chemicals are purged to wastewater collection systems, the requirement to control emissions from the collection system should reflect consideration of the emission potential of the chemical after mixing with water. Therefore, the provisions in §63.166 (b)(4)(i) have been clarified to require control of purges containing any of the chemicals listed in Table 9 of subpart G. If the purged materials do not contain any of the chemicals listed in Table 9 of subpart G and the wastewater will be treated subsequent to discharge to a waterway, then the owner or operator may send the material to any wastewater management unit.

5. Safety Issues with §§63.163, 63.167, and 63.173.

Comment: Three commenters (A-90-20: VI-D-12; VI-D-14; and VI-D-15) supported the proposal to add unsafe to monitor provisions for pumps, and to add provisions for inaccessible and difficult to monitor agitators. One commenter (A-90-20: VI-D-15) remarked these provisions are necessary and appropriate.

Response: None required.

Comment: Several commenters (A-90-20: VI-D-12; VI-D-14: VI-D-15; and VI-D-19) supported the proposed changes to §63.167. Two of these commenters (A-90-20: VI-D-15 and VI-D-19) noted that §63.167 (e) should refer to valves which if capped or plugged would present a serious hazard rather than prevent a serious hazard. These commenters recommended that

the EPA correct this typographical error in the final amendments.

Response: The typographical error has been corrected in the final amendments.

Comment: One commenter (A-90-20: VI-D-19) recommended that the words "including double block and bleed systems" be added after the word "valves" in the first sentence.

Response: The proposed paragraph §63.167 (e) was not revised as suggested by the commenter because the provisions of this section of subpart H only apply to open-ended valves or lines. Therefore, there is no need to include double block and bleed systems in this exemption. This comment did, however, point out the need to amend §63.167(a)(1) to cross reference the new exemption in §63.167(e). This oversight is corrected in the final amendments to the rule.

6. Use of Data Collected Before April 22, 1994.

Comment: Three commenters (A-90-20: VI-D-12; VI-D-14; and VI-D-15) supported the proposal to allow use of data collected before April 22, 1994 to qualify for less frequent monitoring of valves. These commenters thought the proposed change was appropriate.

Response: None required.

7. Proposed Revision of §63.174(h)(1).

Comment: Two commenters (A-90-20: VI-D-14 and VI-D-15) supported the proposed revision of §63.174(h)(1) to refer to the more generic terminology "ceramic or ceramic-lined" connector in lieu of "glass or glass-lined" connector. Both commenters observed that glass was not the only ceramic material of concern and that it would be appropriate to extend these provisions to other ceramic materials.

Response: None required.

8. Proposed Clarification of §63.180 (b)(4)(iii).

Comment: One commenter (A-90-20: VI-D-12) thought that while the proposed clarifications to the calibration requirements help, these provisions still require clarification. This commenter (A-90-20: VI-D-12) requested clarification of whether all calibration scales must be calibrated each day of usage even though monitoring may be devoted to use of only one scale on any given day. The commenter (A-90-20: VI-D-12) suggested that the EPA include one or more examples to explain the intent of the requirement.

Response: The language in §63.180 (b)(4)(iii) has been further revised to clarify that it is not necessary to calibrate every scale on multiple scale instruments if only one scale is used on that day's monitoring. The purpose of the proposed revision to the language was to clarify the requirements for the calibration gases and not to impose a requirement to calibrate scales that are not used.

9. Proposed Amendments to Pressure Tests for Batch Process Equipment.

Comment: Three commenters (A-90-20: VI-D-14; VI-D-15; and VI-D-17) supported the proposed amendment to allow pressurization to less than the set pressure of any pressure relief valve or less than safe pressure limits of the equipment and the proposed amendment to allow use of a pressure gauge with a precision of ±10 percent of the test pressure. These commenters observed that these changes are minor revisions that are needed to account for the practicalities that have been discovered with these procedures.

Response: None required.

10. Proposed Changes to Subpart I to Add Compliance Dates for Changes and to Add Definitions for Process Unit and Source.

Comment: Two commenters (A-90-20: VI-D-14 and VI-D-15) supported the proposed changes to specify compliance dates for operational changes and the proposed definitions for "process unit" and for "source."

Another commenter (A-90-20: VI-D-17) observed that the concept of process unit is not particularly useful for regulating the pharmaceutical industry because most pharmaceutical operations do not fit the conceptual design.

The commenter (A-90-20: VI-D-17) noted that the concept is integrally woven throughout subpart I and that they were interested in clarifying application of the concept not eliminating it. This commenter (A-90-20: VI-D-17) identified three areas where the concept was unclear and presented implementation problems. The first source of ambiguity is that a process unit is defined as a fixed set of equipment to manufacture a product. A flexible pharmaceutical operation may produce numerous products in a year and the boundaries of the process unit could vary from week to week. To address this problem, the commenter suggested that the EPA revise the definition of pharmaceutical process unit to be a set of equipment that manufactures one or more pharmaceutical intermediate or final products. The second ambiguity noted by the commenter is that equipment in pharmaceutical production may not be connected by pipes or ducts; materials may be transferred in closed containers. The commenter suggested that the EPA revise the definition of process unit to include all equipment collocated in the same building or structure, regardless of whether the equipment is connected by pipes or ducts. This commenter (A-90-20: VI-D-17) also requested that the EPA clarify the relationship of the solvent distribution system and the process unit. The commenter questioned whether multiple process units served by a common solvent distribution system would be considered to be a single process unit.

Response: The EPA agrees with commenter (A-90-20: VI-D-17) that the proposed definition of "process unit" was derived from rules for chemical production processes and that this concept may not be appropriate for some pharmaceutical production processes. The EPA also agrees that the best solution is to try to clarify the application of this concept to pharmaceutical processes since this concept is integral to subpart I (and subpart H). The following changes were made in this effort to clarify the proposed language.

The definition for "pharmaceutical production process" was revised to refer to the set of equipment that manufactures one or more pharmaceutical intermediate or final products. This change was made to clarify that the process may produce more than one intermediate or final product.

The definition for "process unit" was revised to eliminate the reference to equipment connected by pipes or ducts. The revised definition reads:

> Process Unit means the group of equipment items used to process raw materials and to manufacture a product. For the purposes of this subpart, process unit includes all unit operations and associated equipment (e.g., reactors and associated product separators and recovery devices), associated unit operations (e.g., extraction columns), any feed and product storage vessels, and any transfer racks for distribution of final product.

As revised, the definition should be more applicable to pharmaceutical production processes than the proposed definition while remaining relevant to other processes subject to subpart I.

The EPA did not revise the definition for "process unit" to refer to all equipment located in the same building or structure (as suggested by the commenter) since this concept may not be appropriate for all pharmaceutical processes or for the other processes subject to subpart I. The EPA does agree with the commenter that additional options for definition of a process unit are necessary for flexible pharmaceutical production processes that frequently reconfigure equipment to make different products. Therefore, a new provision has been added to §63.192, as paragraph (a)(2), that will allow an owner or operator of a pharmaceutical production process several alternatives for defining a process unit for purposes of compliance with subpart I. The new provisions allow an owner or operator to define the process unit as the equipment dedicated to the production of a product, as all operations located within a building or structure, or as all operations within a source. This change is consistent with the regulatory negotiation committee's intention to provide a workable equipment leak program for pharmaceutical processes.

Comment: One commenter (A-90-20: VI-D-20) suggested that the text in proposed §63.190(g)(4)(ii) be reorganized to allow the option of extra compliance time to the provisions addressed in paragraph (g)(4)(ii)(A) and (g)(4)(ii)(B). The commenter (A-90-20: VI-D-20) noted this change would provide consistency between these provisions and subpart F.

Response: Since these provisions apply to existing sources only, the EPA agrees with the commenter that this change is appropriate and necessary. The final amendments reflect the commenter ′s suggested revision.

11. Proposed Clarification of the Definition of "Pharmaceutical Production Process."

Comment: Three commenters (A-90-20: VI-D-14; VI-D-15; and VI-D-17) supported the proposed clarification that solvent recovery operations are not within the definition of "pharmaceutical production process." One of these commenters (A-90-20: VI-D-17) also requested clarification that waste storage, treatment, or disposal operations that receive waste from pharmaceutical production processes are not subject to subpart I.

Response: As discussed in the preamble to the proposed amendments to subparts H and I, the provisions of subpart I were intended to apply only to those pharmaceutical production processes that synthesize a pharmaceutical intermediate or product. Collocated solvent recovery operations or waste storage, treatment, or disposal operations are considered to be separate operations from the pharmaceutical production process and thus not subject to subpart I (60 FR 18074).

12. Proposed Exemption of Bench Scale Processes from Applicability of Subpart I and Subpart H.

Comment: Two commenters (A-90-20: VI-D-14 and VI-D-15) agreed with the proposed exemption of bench scale batch process equipment from subpart I and the proposed definition of bench scale batch process. These commenters thought that the equipment leak provisions of subpart H are inappropriate for such equipment. One of these commenters (A-90-20: VI-D-15), however, thought that the exemption and definition should be placed in subpart H not subpart I. This commenter (A-90-20: VI-D-15) agreed that while the only known example identified so far is in the pharmaceutical industry, they expect that similar situations could arise in other industries. This commenter reasoned that since subpart H is being used as a generic equipment leak rule, it would be more efficient to place the exemption in subpart H.

Response: Although the EPA does not know if there will be any need for this exemption in subpart H, the EPA agrees with commenter (A-90-20: VI-D-15) that it would be more efficient to add it to subpart H now than to wait. The EPA decided against the commenter's suggestion to remove the definition and exemption from subpart I because this provision

does define applicability of subpart I. If this exemption were removed from subpart I, some sources might be subject to additional recordkeeping and reporting requirements. To eliminate any possibility for confusion on this point, the EPA has decided the definition and exemption should be stated in subpart H and I.

Comment: One commenter (A-90-20: VI-D-16) suggested that the EPA modify the first sentence of the proposed definition to read:

> Bench-scale batch process means a batch process (other than a research and development facility) that is operated on a small scale, such as one capable of being located on a laboratory bench top. This bench scale equipment ...

The commenter (A-90-20: VI-D-16) thought that including this suggested language would more accurately reflect the conditions discussed in the preamble and preclude possible misinterpretation of the EPA's intent.

Response: The EPA agrees with the commenter that the proposed definition was more restrictive than suggested in the preamble discussion. Since the preamble to the proposed amendments accurately expressed the intent of the proposed provisions, the final definition has been revised as suggested by the commenter.

Attachment

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